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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,500	12/02/2005	Jean-Pierre Abastado	IDM0016-301-US	3483
72300 7590 03/28/2008 GLOBAL PATENT GROUP - IDM Ms. LaVern Hall 10411 Clayton Road, Suite 304 ST. LOUIS, MO 63131				
EXAMINER SAUNDERS, DAVID A				
ART UNIT		PAPER NUMBER		
1644				
MAIL DATE		DELIVERY MODE		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/537,500

Applicant(s)

ABASTADO ET AL.

Examiner

David A. Saunders

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 50-98 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 50-98 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-946)
- 3) ☐ Information Disclosure Statement(s) (PTO/SE/US)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

AMENDMENT ENTRY

Amendment of 6/3/05 has been entered. Claims 50-98 are pending. Claims 50-98 are under subject to an election of species as stated further infra.

Claims 51, 53 and 79 filed on 6/3/05 are confusing for the following reasons:

Claim 51 depends from cancelled claim 1. For purposes of stating the election of species, The Office assumes that applicant intended dependency from Claim 50.

Claim 53 is self-dependent. For purposes of stating the election of species, The Office assumes that applicant intended dependency from Claim 52.

Claim 79 depends from cancelled claim 28. For purposes of stating the election of species, The Office assumes that applicant intended dependency from Claim 78.

ELECTION OF SPECIES

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

- I. a potency assay for a composition of purified APCs, or a batch release assay of a composition of purified APCs, or an inclusion criterion for a patient wherein the composition of purified APCs originating from said patient have the ability to induce a proliferation of T lymphocytes.
- II. a method to evaluate the effect, on a T-cell response, of one or more cytokines secreted by a composition of purified APCs.
- III. a method to evaluate the effect, on a T-cell response, of one or more surface determinant markers present on T-cells.
- IV. an antigen selecting assay wherein the antigen to be tested is loaded on purified APCs.
- V. a method to define a standard control T-cell response of T-lymphocytes.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

- I. Claims 77-80, 87-89
- II. Claims 81-83
- III. Claims 84-86
- IV. Claims 90-91
- V. Claims 92-98

The following claim(s) are generic:

Claims 51-76 are generic to a plurality of the above listed species.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

In order for there to be Unity of Invention, there must be a single contribution over the prior art. If the invention lacks novelty or an inventive step, there is thus no contribution over the prior art and therefore a lack of Unity of Invention. Instantly the IPEA has found prior art against all of originally filed claims 1-44 and 46-49, which essentially correspond to claims 50 and 52-98 (claim 51 is a conglomeration of claims

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77, 81, 84, 87, 90 and 92). Instantly, all of the species involve a test system in which there is a determination of T-lymphocyte parameters, after the co-culturing of APCs and T-lymphocytes. However, vastly different conclusions are drawn from the results obtained in each of the above listed species. For example, conclusions drawn about the "potency" or the "release" of a composition of APCs are disparate from conclusions drawn about the "effect of cytokines" or the "effect of...surface determinant markers" upon a T-cell response. Likewise, each of the conclusions drawn about the "effect of cytokines" or the "effect of...surface determinant markers" is disparate from the other. All of the forgoing are disparate from a method of "antigen selecting" or "defining a standard control"; and each of these latter is disparate from the other.

A reference showing that one of the species of conclusions can be drawn from such a test system would not necessarily suggest that one or more of the other conclusions could be drawn. Even if there might be reference showing or suggesting more than one of or all of the species, there would be an undue examination burden on the Office, since there would be a need to cite different parts of the same reference and/or to develop different rationals for the consideration of the different species.

The interaction of the co-cultured of APCs and T-lymphocytes can be likened, broadly, to that between an enzyme and a substrate. The patent literature has been well developed in the enzyme art. In that art, there are numerous patents to different inventions. In one patent a substrate can be used to measure the activity of an enzyme in a sample; in another patent the same enzyme can be used to measure the concentration of the substrate in a sample. In another patent the enzyme can be used to screen for new substrates or inhibitors. In like manner, in the instant art of cellular immunology, which is younger than the enzyme art, it is deemed that assays that make conclusions about the nature of APCs, about T-lymphocytes, about antigens etc. should be kept separate from one another.

ADVISORIES TO APPLICANT

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the

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requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

CONTACTS

Any inquiry concerning this communication from the examiner should be directed to David A. Saunders, whose telephone number is 571-272-0849. The examiner can normally be reached on Mon.-Thu. from 8:00 am to 5:30 pm and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara, can be reached on 571-272-0878. The fax phone number for the organization where this application is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Typed 3/21/08 DAS

/David A Saunders/

Primary Examiner, Art Unit 1644